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Commissioner for Patents
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Sir:

The below-identified communication(s) is (are) submitted in the above-captioned application or proceeding:

☒ Certified Copy of Australian Provisional Application No. 2003901869

☒ The Commissioner is hereby authorized to charge payment of any fees associated with this communication, including fees under 37 C.F.R. §§ 1.16 and 1.17 or credit any overpayment to **Deposit Account Number 10-0233-COCH-0051-1.**

Respectfully submitted,

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August 2, 2004

Patent Office
Canberra

I, JULIE BILLINGSLEY, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. 2003901869 for a patent by COCHLEAR LIMITED as filed on 17 April 2003.

WITNESS my hand this
Fifth day of May 2004

J. Billingsley

JULIE BILLINGSLEY
TEAM LEADER EXAMINATION
SUPPORT AND SALES

AUSTRALIA

Patents Act 1990

Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

Manual insertion tool for a cochlear implant

The invention is described in the following statement:

"Manual insertion tool for a cochlear implant"

Technical Field

The present invention relates to a surgical tool for use in microsurgical situations requiring manipulation of a tubular element in very small, delicate, and confined spaces. In particular, the present invention relates to a surgical tool that can be used to aid surgeons during implantation of cochlear electrode arrays during a cochlear implant surgical procedure.

Background of the Invention

The use of implantable medical devices to apply therapy to the body is becoming increasingly common as the benefit that such devices provide, become fully realised. Typically, such devices require the implantation and strategic placement of electrode arrays close to sensitive structures of the body to apply stimulation thereto, typically in the form of electrical or mechanical stimulation. Devices such as cardiac pacemakers, cochlear implants and implantable hearing aids are all typical examples.

Often, the procedure for implanting and locating the devices within the body requires much skill by the surgeon and the dexterous use of existing surgical tools to achieve the desired device placement. The implantable elements are also often of a size and shape that increases the difficulty of their handling, and the tools that are employed to handle such devices are generally not specifically designed to perform the given task. An example of the type of tools typically used in such procedures are standard jeweller's forceps or micro-scissors which may not be readily adaptable for use and application to the medical devices.

In terms of cochlear implants, it has been proven that electrical stimulation of the cochlea using cochlear implant systems can be used to directly deliver electrical stimulation to the auditory nerve fibres, thereby allowing the brain to perceive a hearing sensation resembling the natural hearing sensation normally delivered to the auditory nerve.

Cochlear implant systems have typically consisted of two main components, an external component commonly referred to as a processor unit and an internal implanted component commonly referred to as a receiver/stimulator unit. Traditionally, both of

these components have cooperated together to provide the sound sensation to a recipient.

The external component has traditionally consisted of a microphone for detecting sounds, such as speech and environmental sounds, a speech processor that converts the detected sounds, particularly speech, into a coded signal, a power source such as a battery, and an external transmitter antenna.

The coded signal output by the speech processor is transmitted transcutaneously to the implanted receiver/stimulator unit situated within a recess of the temporal bone of the recipient. This transcutaneous transmission occurs via the external transmitter antenna which is positioned to communicate with an implanted receiver antenna provided with the receiver/stimulator unit.

This communication serves two essential purposes, firstly to transcutaneously transmit the coded sound signal and secondly to provide power to the implanted receiver/stimulator unit. Conventionally, this link has been in the form of a radio frequency (RF) link, but other such links have been proposed and implemented with varying degrees of success.

The implanted receiver/stimulator unit traditionally includes a receiver antenna that receives the coded signal and power from the external processor component, and a stimulator that processes the coded signal and outputs a stimulation signal to an intracochlear electrode assembly mounted to a carrier member which applies the electrical stimulation directly to the auditory nerve producing a hearing sensation corresponding to the original detected sound.

The carrier member, including the intracochlear electrode assembly, is typically placed within a duct of the cochlea referred to as the scala tympani. The procedure for performing this task and ensuring that the assembly is correctly positioned within the cochlea is a relatively difficult one requiring much skill and care on behalf of the surgeon.

To position the electrode assembly, a surgeon must first access the cochlea and this is typically done by performing a mastoidectomy and posterior tympanotomy, followed by a cochleostomy to create an opening to the cochlea with which the

assembly is to be inserted. The assembly is then inserted by gripping the member by hand or with a tool and inserting a leading end of the carrier through the cochleostomy and into preferably the scala tympani of the cochlea.

One potential problem during the insertion process is the potential for the carrier member to irreversibly damage the auditory nerve fibres of the cochlea, which may be due to an uncontrolled or an unstable insertion procedure. Conventionally, the carrier member is inserted along the line of sight through the round window and along the basal turn of the cochlea, with the force and direction of the insertion procedure controlled through the use of conventional alligator forceps or with Y-shaped surgical claws. Such conventional insertion tools are not specifically designed to handle such a carrier member and as such there is increased risk of the carrier member moving during the insertion procedure. With conventional sharp tipped or alligator forceps, the contact area between the carrier member and the tips of the forceps is also quite small and may not necessarily constrain the carrier member against movement. In such instances, it is possible for the carrier member to swing between the tips of the forceps, thereby reducing the surgical control associated with the current technique. Such tools are also not designed to cater for the typical procedure associated with cochlear implantation, and as such are not typically dimensioned and shaped to deal with the delicate structures of the middle and inner ear. Further to this, as conventional tools are not specifically designed to handle a cochlear implant carrier member, the forces that they apply to the carrier member may increase the risk of damage occurring to the delicately arranged electrode elements and wires.

The present Applicant has previously proposed an apparatus and method for assisting in the controlled and safe insertion of a cochlear electrode assembly as described in U.S. Patent 4,898,183. This proposal was directed at providing the electrode assembly with a resilient collar which could be manipulated during the insertion process by a simple round ended gripping tool to aid in advancing the assembly into the cochlea. This proposal required the design of the assembly to be adapted, rather than the design of the insertion tool, and as such failed to address the problems associated with using prior art surgical tools to aid in the insertion of intracochlear electrode arrays.

Further prior art is disclosed in US Patent No. 6,096,059 to Kuzma, which describes a microsurgical forceps tool for use in precision surgery in small confined

spaces. The described tool is designed to enable precise micro-manipulation through simple and slight movements of the fingers and wrist due to a leaf spring arrangement activating a pair of jaws. Whilst the described tool could be used for the insertion of intracochlear electrode arrays, the tool itself is more directed towards the actuation mechanism for grasping and releasing the jaws rather then a tool adapted to assist in the specific process of electrode assembly insertion. As such, the mechanism of the described device is difficult to control and has an increased potential to damage the delicate structure of the electrode array during insertion.

The present invention therefore provides a surgical tool that is designed to hold a rod shaped element and allow easy manipulation of the element in a microsurgical environment.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

According to a first aspect, the present invention is a tool for manipulating an elongate tubular member comprising two arms extending from a common join to respective distal tip regions, each distal tip region having a length and further having a substantially constant width over that length, said arms being relatively movable towards and away from each other so as to bring the distal tip regions at least adjacent each other to grasp and manipulate the elongate tubular member.

In a preferred embodiment, the tool can be adapted to grasp elongate carrier members for electrode arrays, such as electrode arrays that are to be implanted within the cochlea of a recipient.

According to a second aspect, the present invention is a tool for manipulating an elongate tubular member comprising two arms extending from a common join to respective distal tip regions, one of the distal tip regions having a substantially flat face and the other having a half-tube member, said arms being relatively movable towards and away from each other so as to bring the distal tip regions at least adjacent each other to grasp and manipulate the elongate tubular member.

The half-tube member preferably provides a larger contact area to more firmly constrain the body of an electrode array therebetween, with the holding force being applied by the flat face of the opposing tip of the tool. This therefore provides improved surgical control of the orientation of the electrode array during the insertion procedure, thereby providing a procedure where potential damage to the sensitive structure of the cochlea is relatively minimised, as is damage to the structure of the electrode array, through mishandling.

As mentioned, the flat tip face of the clasping tip aids in constraining the tubular element within the half-tube member of the other clasping tip. As, in the case of cochlear implants, there is often a very confined space within which the tool must operate, the flat face allows for easy release of the electrode element in the confined space, then would be the case should both tips be of a half-tube configuration.

The flat tip face is preferably wider than the outer diameter of the opposed half-tube member. This ensures that if the tool is to be used to handle an electrode array that is thinner than the half-tube region, then the tool will not squash the electrode array when there is force placed upon the handle of the tool by the surgeon.

The half-tube member can have a variety of suitable geometries. In one embodiment, the half-tube member can be semi-circular. It is envisaged that the half-tubular member could comprise part of a square, a hexagon or triangle, to receive the tubular member therein.

The thickness of the half-tube member is preferably about 0.1mm. Tools having regions thinner than this may suffer from reduced tip strength resulting in an inability of the tool to firmly grasp the tubular element, and with thicker regions may adversely affect the visibility of the user when manipulating the device.

The length of the half-tube member is preferably between about 0.8-1.2mm, which is preferably long enough to stably hold a tubular element such as an electrode array, and yet short enough to maintain flexibility of use of the tool. Typically, the half-tube region is designed such that it subtends an arc of less than or equal to 180°. Any greater than this and it would cause difficulties placing the electrode array into the tool.

In a further embodiment, a cut-out section can be provided centrally of the half-tube member to aid in the user's visibility of the tip of the tool.

The join between the half-tube member and the remainder of that distal tip region can be relatively abrupt or can be relatively smooth. It is preferred that sharp angles of the tool are minimised, and as such the risk of the catching the tool on the electrode element during removal of the tool is reduced.

According to a third aspect, the present invention is a tool for manipulating an elongate tubular member comprising two arms extending from a common join to respective distal tip regions, one of the distal tip regions having a substantially flat face and the other having a forked or looped region, said arms being relatively movable towards and away from each other so as to bring the distal tip regions at least adjacent each other to grasp and manipulate the elongate tubular member.

In this embodiment, the substantially tubular electrode array is preferably able to be securely held between the forked region and the flat face of the opposing clasping tip, in a similar manner as is achieved with a half-tube member described above.

Where one of the tips has a looped region, this tip is preferably bent away from the flat face tip so that the tip does not contact the electrode before the looped region contacts the electrode.

In both of the second and third aspects, the clasping distal tip regions are generally formed with one shaped tip capable of receiving a tubular element therein and an opposed flat tip acting together with the shaped tip to maintain the tubular element securely therebetween. It should be appreciated that a variety of shapes, other than flat, could be used on the opposing tip and still remain within the spirit of the present invention. For example, the flat face could be replaced with a convex face or a concave face.

According to a fourth aspect, the present invention is a tool for manipulating an elongate tubular member comprising two arms extending from a common join to respective distal tip regions, each of the distal tip regions having an identical concave member, said arms being relatively movable towards and away from each other so as to bring the distal tip regions at least adjacent each other to grasp and manipulate the elongate tubular member.

In this aspect, the tips, when brought together, define a region where a tubular element such as an electrode array, can be maintained securely by the tips.

In one embodiment of this aspect, the tips can have a substantially curved V-shaped grooved end region that preferably optimises the grip between the two acting tips when brought together about a tubular member.

In a preferred embodiment of all of the aspects, the respective arms are joined together at a proximal end of the tool. The arms are preferably biased such that the distal tip regions are positioned apart when the tool is in a relaxed position. Compressive force applied to one or both arms of the tool can then preferably bring the arms relatively towards each other and so allow grasping of elongate members between the respective distal tip regions.

In a preferred embodiment of all of the aspects, the respective arms have the same length and are straight. The distal tip regions preferably extend forwardly from the arms but an angle to the longitudinal axis of the straight portions of the arms. The angle is preferably between 0 and 25°, but is more preferably about 18°.

The tool preferably has a length of about 152mm and, at its widest extent, a width of about 10mm. The tool is preferably widest at and/or adjacent its proximal

end. The length of the respective distal tip regions are preferably the same. In one embodiment, the length can be between about 5 and 15mm, more preferably about 9mm.

The tool is preferably made from a metal, such as 304 Stainless steel, however the tool could also be made from a ceramic material using a material such as alumina. The tool is preferably reusable following appropriate sterilisation. However, it is also envisaged that the tool could be disposable following use, and in this regard the tool could be made of a plastic, such as PEEK, ABS, PMMA or Polyimide.

The present invention provides a surgical tool capable of performing delicate manual microsurgical procedures with stability and control. Unlike more conventional surgical tools, the present invention provides clasping tip regions specifically designed to receive tubular elements such as electrode arrays and to enable handling of such elements in both a secure and stable manner as well as in a manner that will not damage the delicate structures of the elements.

Brief Description of the Drawings

By way of example only, preferred embodiments of the invention are now described with reference to the accompanying drawings, in which:

Fig. 1 is a view of the implanted componentry of a typical cochlear implant system;

Fig. 2 is a simplified view of an electrode array of the cochlear implant system of Fig 1;

Figs. 3a, 3b and 3c are a perspective, side and top view of one embodiment of the surgical tool of the present invention;

Fig. 4 is a perspective view of one embodiment of the clasping tips of the surgical tool of Fig. 3;

Fig. 5 is a top, end and side view of the half-tube arrangement of the clasping tip of Fig 4;

Fig. 6 is a top, end and side view of an alternative half-tube arrangement of the clasping tip of Fig. 4;

Fig. 7 is various views of yet another embodiment of the alternative half-tube arrangement of the clasping tip of Fig 4;

Fig. 8 is a cross-section end view of another embodiment of the clasping tip arrangements of the present invention;

Fig. 9a and 9b are views of further embodiments of the clasping tips of the present invention;

Fig. 10 represents various embodiments of the flat tip region of the present invention;

Fig. 11 represents another embodiment of the clasping tip arrangements of the present invention;

Fig. 12 is a view of the clasping tip arrangements of Fig. 11 used to hold a conventional cochlear implant electrode array;

Fig. 13 is an end view of the clasping tip arrangements of Figs. 11 and 12; and

Fig. 14 is a side view of the clasping tip arrangements of Figs 11 and 12.

Best Mode for Carrying out the Invention

The implanted componentry of a typical cochlear implant system is shown in Fig. 1. Cochlear implants usually consist of an implanted receiver/stimulator package 2, a receiver antenna coil 4, and an intracochlear electrode array 6, which is typically implanted in the scala tympani of the cochlea. In operation, the implanted receiver/stimulator package 2 contains the relative electrical circuitry to convert coded signals received from the external speech processor (not shown) into stimulation pulses to be applied by a selected electrode strategically placed within the cochlea. In this regard, the receiver antenna coil 4 receives the coded signal from an external

transmitter antenna coil (not shown) aligned therewith via a transcutaneous radio frequency (RF) link. Alignment of the external transmitter antenna coil with the implanted receiver antenna coil 4 is typically achieved by the provision of magnets 8 placed centrally of the antenna coil and magnetically holding the coils in place for transmission to occur.

As is shown in Figure 2, the intracochlear electrode array typically consists of a plurality of electrode elements 12, encapsulated in an electrode carrier member 14, made from a flexible material, such as silicone. Each of the electrode elements 12 is typically connected by at least one conductor element or wire (not shown), electrically connecting the electrode element 12 to the receiver/stimulator package 2. In this regard, the electrode array 6 is typically of a flexible, substantially tubular configuration having a substantially oval or circular cross-section. In a preferred form, the electrode array 6 is preferably constructed in a pre-curved configuration to conform to the natural spiral shape of the cochlea, and held in a straight configuration for insertion through the use of a stiffening stylet (not shown) which extends substantially the length of the electrode array 6.

Figure 3a is a perspective view and Figures 3b and 3c are side and top views, respectively, of one embodiment of the manual electrode insertion tool according to the present invention.

The tool, generally referred to as 20, in some ways resembles a common pair of forceps or tweezers, having a main body 22 which branches into two relatively flexibly movable arms 24 and 26. The two flexible arms 24 and 26 terminate at end 21 in respective clasping tips 29, which are adapted to hold or capture a substantially tubular element, such as a cochlear implant electrode array 6, therebetween. The two arms 24 and 26 are fixed together with respect to each other at one end 25, and are biased such that the clasping tips 29 of the arms 24 and 26, when in a relaxed position, are positioned remote from each other at end 21. In this regard, the clasping tips 29 can be brought together by applying a compressive force on the arms 24 and 26 to hold or capture an element between the clasping tips 29.

As is evident in Figs. 3a and 3c, the clasping tips 29 are positioned at an angle offset from the longitudinal axis of the tool 20. This angle is shown in Fig. 3c as being an angle (Φ) and can be any angle between 0 and about 25°, more preferably about 18°.

As is further evident from these figures, the clasping tips 29 are provided with an elongated, constant small diameter section that differs significantly from standard forceps/tweezers, which typically gradually increase in cross section from the tip back to the main body of the tool. The length of the offset clasping tips 29 can vary depending upon the use of the tool, but the length may be preferably between about 5-15mm, more preferably about 9mm.

The purpose of the angled and elongated, constant small diameter section of the clasping tips 29 allows improved access and manipulation of the tool and any tubular element held by the tool. In particular, the purpose of the region of the clasping tips 29 allows the tool to be used in areas where there is restricted access for conventional surgical tools, such as to gain access through the posterior tympanotomy in a cochlear implantation procedure. The angled tips provide improved visibility of the site to the surgeon whilst being straight enough to allow a precise "dart like" manipulation of the tool.

The tool 20 is preferably made from a metal such as 304 Stainless steel, however the tool could also be made from a ceramic material using a material such as alumina. Such a device would allow re-usability of the tool following surgical use and sterilisation. However, it is also envisaged that the tool could be disposable following use, and in this regard the tool could be made of a plastic, such as PEEK, ABS, PMMA or Polyimide.

Figure 4 shows in more detail the angled and elongated, constant small diameter section of the clasping tips 29 of the present invention according to one embodiment. As is shown, the clasping tips 29 are designed to cooperate together to securely and safely hold and maintain in control a substantially tubular element therebetween, such as a cochlear implant electrode array. In this particular embodiment, one of the tips is provided with a substantially flat face 32, with the other tip provided with a substantially half-tube region 34.

This differs substantially from presently used surgical forceps or tweezers where the tips are substantially sharp, flat ends. With such tools, it has been found that when they are employed to grip an element, such as a substantially tubular electrode array 6 as that shown in Fig. 2, the contact area between the electrode array and the forcep tips

is quite small and does not sufficiently constrain the electrode array between the ends of the tool, resulting in the array easily swinging between the two tips.

In the present invention, and in the embodiment shown in Fig. 4, the half-tube region 34 provides a larger contact area to more firmly constrain the body of the electrode array therebetween, with the holding force being applied by the flat face 32 of the opposing tip of the tool. This therefore provides improved surgical control of the orientation of the electrode array during the insertion procedure, thereby providing a procedure where potential damage to the sensitive structure of the cochlea is relatively minimised, as is damage to the structure of the electrode array, through mishandling.

As mentioned, the flat tip face region 32 of the clasping tip aids in constraining the tubular element within the half-tube region 34 of the other clasping tip. As, in the case of cochlear implants, there is often a very confined space within which the tool must operate, the flat tip region allows for easy release of the electrode element in the confined space, then would be the case should both tips be of a half-tube configuration. It has been found that with such a configuration shown in Fig 4, the arms of the tool can be easily opened, even in instances where the space for doing so is limited, such as within a posterior tympanotomy. The flat tip face region 32 is preferably wider than the outer diameter of the opposed half-tube region 34. This ensures that if the tool is to be used to handle an electrode array that is thinner than the half-tube region, then the tool will not squash the electrode array when there if force placed upon the handle of the tool by the surgeon.

Figure 5 shows approximate dimensions of the half-tube region of the clasping tips according to the embodiment shown in Fig 4. As can be appreciated, the geometry of the half-tube region can be altered to optimise the holding capabilities of the tool, without adversely affecting the visibility of the user of the tool. Preferably, the thickness of the half-tube region is 0.1mm. Tools having regions thinner than this may suffer from reduced tip strength resulting in an inability of the tool to firmly grasp the tubular element, and with thicker regions may adversely affect the visibility of the user when manipulating the device.

The length of the half-tube region is preferably between 0.8-1.2mm, which is long enough to stably hold a tubular element such as an electrode array, and yet short enough to maintain flexibility of use of the tool. Typically, the half-tube region is

designed such that it subtends an arc of less than or equal to 180°. Any greater than this and it would cause difficulties placing the electrode array into the tool. Whilst the embodiments shown represent semi-circular shapes, it is envisaged that the half-tubular regions could equally be made of a square, hexagonal or triangular shape, to receive the tubular member therein.

Figure 6 shows an alternative form of the half-tube region 34 of Fig 4. In this embodiment, a cut out section 35 is provided centrally of the region 34 to aid in the user's visibility of the tip of the tool.

Figure 7 shows another alternative embodiment of the present invention adapted to provide a gradual conversion from the straight section 38 of the arm to the half-tube region 34. In this embodiment all sharp angles of the tool are minimised, and as such the risk of the catching the tool on the electrode element during removal of the tool is reduced.

Figure 8 shows an alternative embodiment of the configuration of the clasping tips 29 of the tool of the present invention. In this embodiment, the clasping tips are still designed to firmly maintain a tubular element therebetween, however instead of a half-tube region receiving the tubular element, a forked or looped region is employed to act with the flat region of the opposed tip. In this embodiment, and as is shown in Figure 8, the substantially tubular electrode array 6 will be securely held between the fork elements 42 and a flat face region 48 of the opposing clasping tip, in a similar manner as is achieved with a half-tube design of Fig. 4.

This configuration of the clasping tips is shown in Fig. 9a in the form of a looped region 44 employed on the upper clasping tip and a flat face region 48 employed on the lower clasping tip. Preferably, the tip of the looped region is bent away from the flat clasping tip (not shown) so that the tip does not contact the electrode before the fork elements of the loop contact the electrode. In the embodiment shown in Figure 9a, the fork elements of the looped region are joined at the tip to form a closed loop, however it should be appreciated that the fork elements may be open at the end resembling an actual fork, as is shown in Fig. 9b.

In each of the above described embodiments, the clasping tips are generally formed with one shaped tip capable of receiving a tubular element therein and an

opposed flat tip acting together with the shaped tip to maintain the tubular element securely therebetween. It should be appreciated that a variety of shapes, other than flat, could be used on the opposing tip and still remain within the spirit of the present invention.

As shown in Figure 10, a variety of shapes could be used such as a flat 51, convex 52, forked/looped 53 or concave 54 region.

Figure 11 and Figure 12 show yet another embodiment of the present invention wherein both clasping tips are configured with an identical concave arrangement. As is shown in Figure 11, when the tips 55 are brought together they define a region where a tubular element such as an electrode array, can be maintained securely by the tips. This is shown in Figure 12, where a cochlear implant electrode array 58 is securely maintained between the clasping tips 55 of the tool.

The tips 55 are shown in dimensional detail in Figures 13 and 14. The tips 55 have been designed with a substantially curved V-shaped grooved end region 60 rather than a half-tube design, to optimise grip between the two acting tips when brought together about a tubular member.

As can be appreciated, the present invention provides a surgical tool capable of performing delicate manual microsurgical procedures with stability and control. This is achieved by providing an angled, elongated, substantially constant small diameter section near the tips of the tools to be manipulated to securely maintain a tubular member therebetween for manipulation during surgery. Unlike more conventional surgical tools, the present invention provides clasping tip regions specifically designed to receive tubular elements such as electrode arrays and to enable handling of such elements in both a secure and stable manner as well as in a manner that will not damage the delicate structures of the elements.

Whilst the present invention was described in relation to a forcep-like tool, the present invention is equally applicable to a pincer-type tool or alligator clamp tool that may be used for grasping elements in a surgical situation. It should be appreciated that the present invention is not limited to the hand-interface aspect of the tool.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this seventeenth day of April 2003

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO

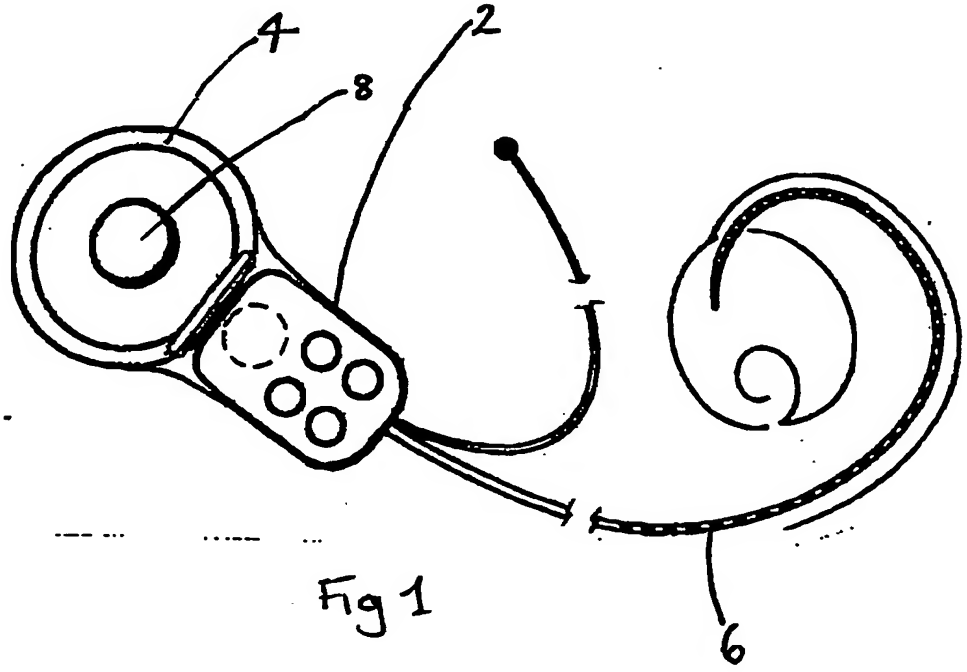


Fig 1

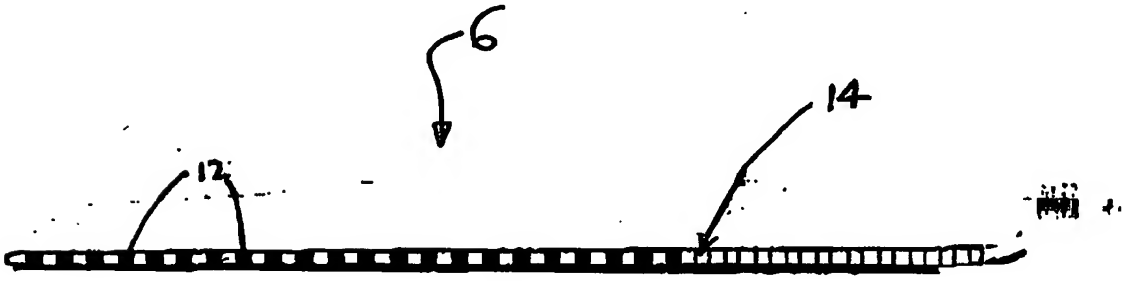


Fig 2

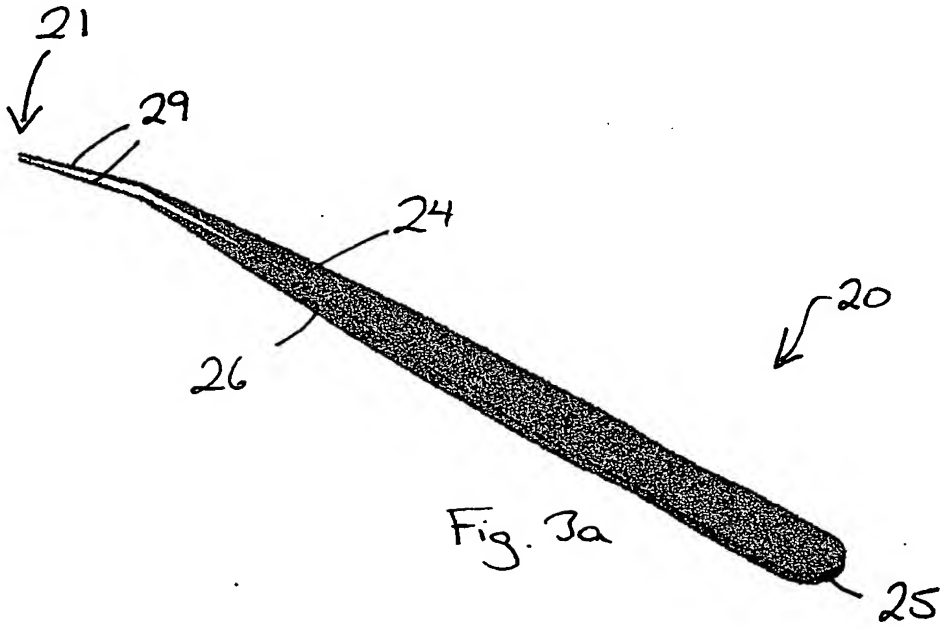


Fig. 3a

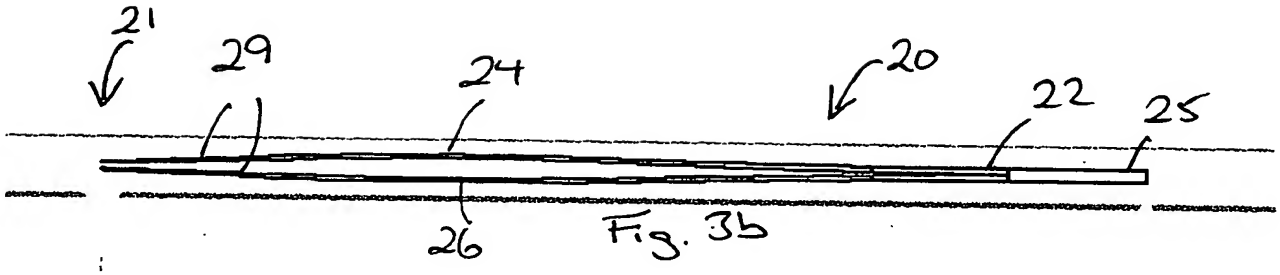


Fig. 3b

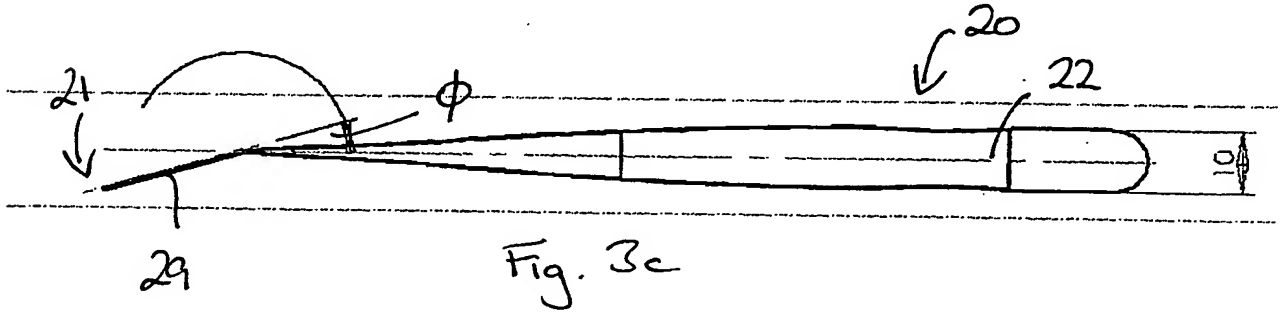


Fig. 3c

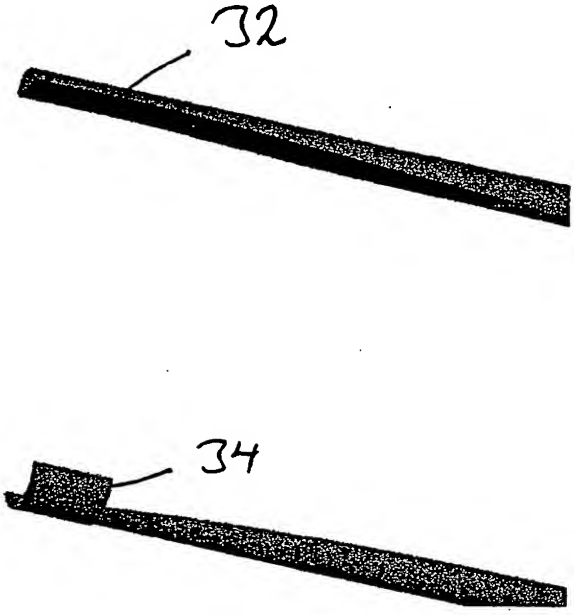


Fig. 4

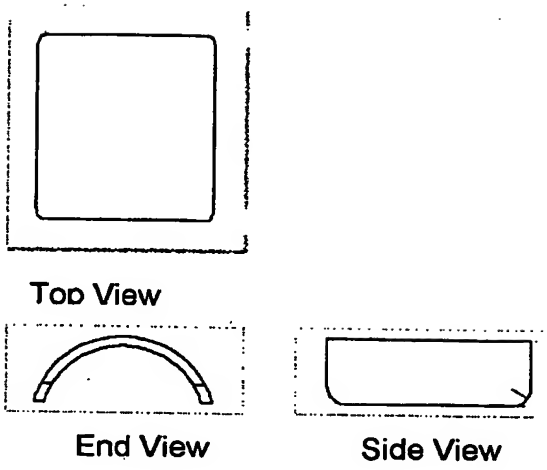


Fig. 5

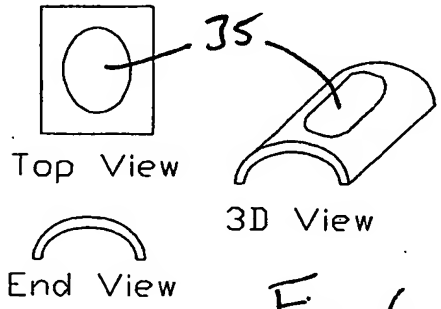
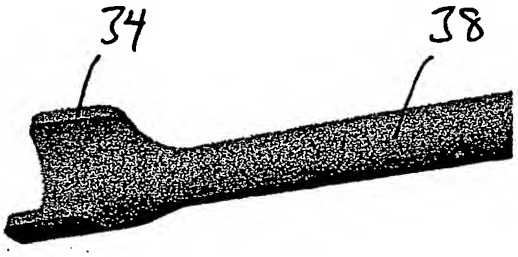


Fig. 6



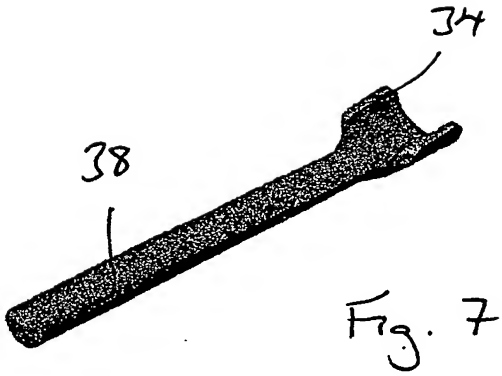


Fig. 7

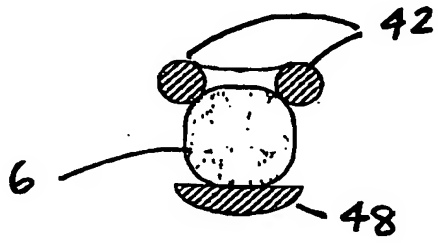


Fig 8

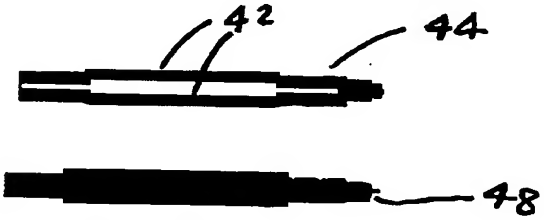


Fig 9a

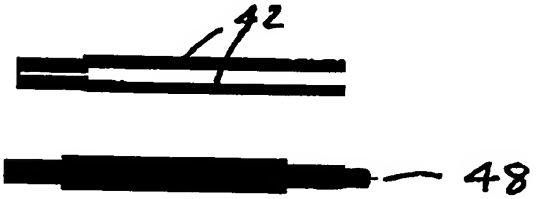


Fig 9b

Fig 10

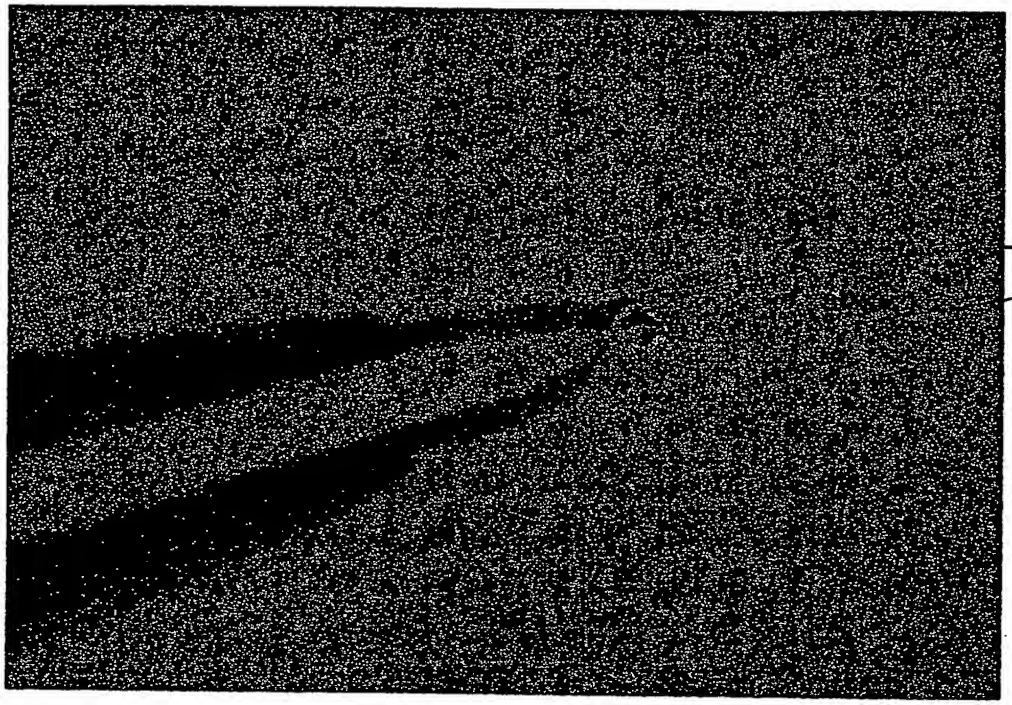


Fig. 11

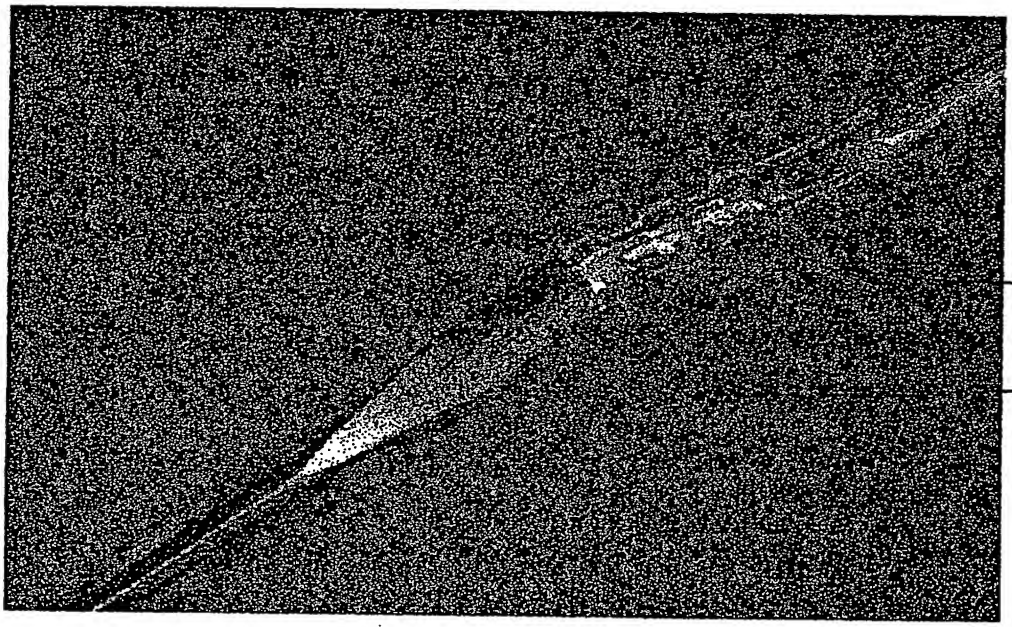


Fig. 12

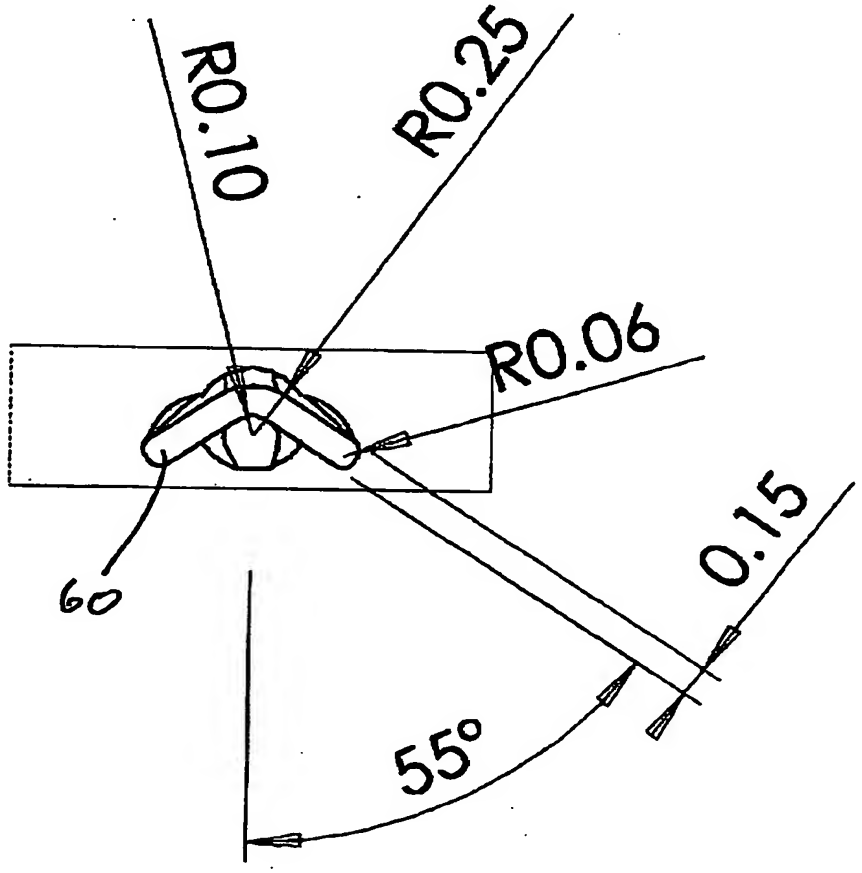


Fig 13

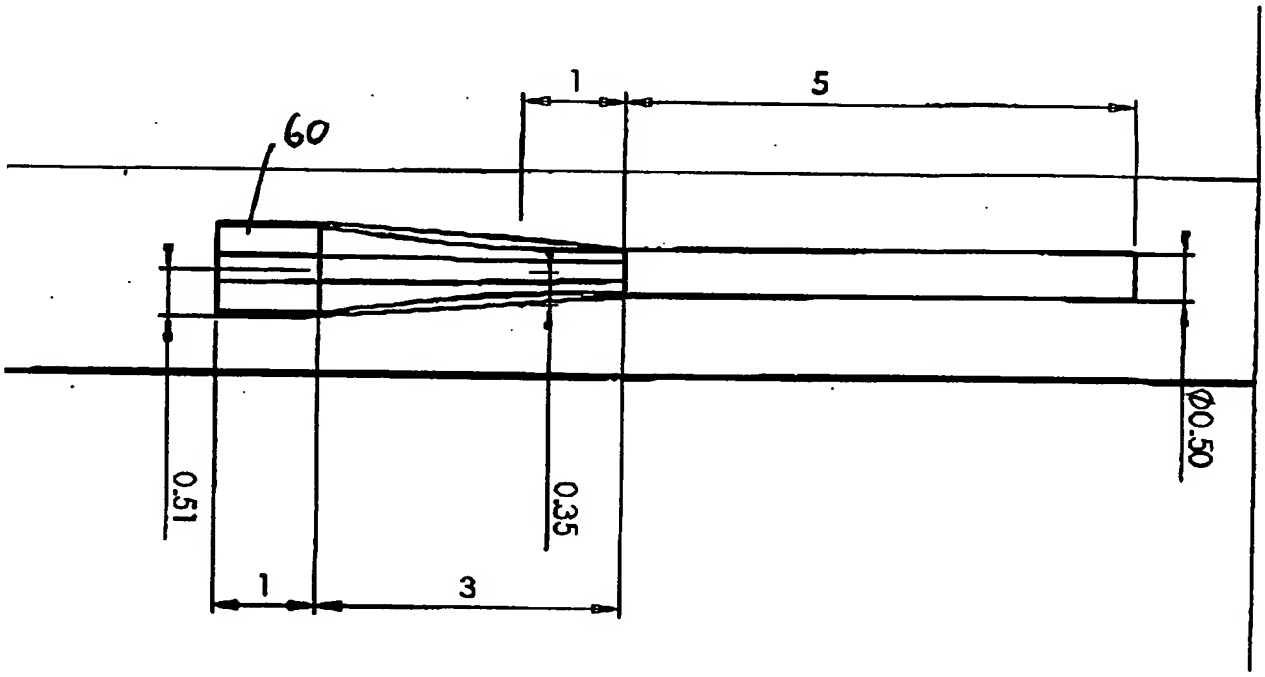


Fig 14